



Lawrence Livermore National Laboratory

November 18, 1992

Jerome E. Dennis, Chief
LightProducts Branch
Division of Standards Enforcement
Office of Compliance and Surveillance
Center for Device and Radiological Health
HFZ-312
1390 Piccard Drive
Rockville, MD 20750

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IS MANAGEMENT BRANCH

REFERENCE: Notice of Consideration of Possible Amendments to the Federal Performance Standard for Laser Products, J.E. Dennis, FDA, 9/23/92

Mr. Dennis:

Thank you for giving the Laboratory the opportunity to comment on possible amendments to the Federal Performance Standard for Laser Products. The Laboratory has comments on the following two proposals:

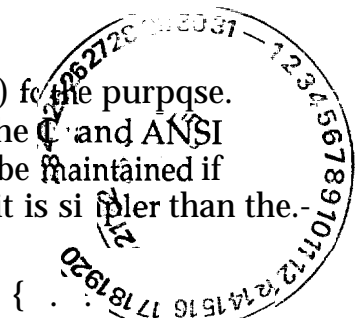
Proposal #3

FDA is proposing to lower the maximum emission duration to be considered, for Class 1 lasers that are not intended to be viewed, to 100 seconds. Classification of lasers for which viewing is intended as Class 1 would still require consideration of exposure durations of 10^4 seconds. For this latter group, a less restrictive criterion is found in the ANSI Z136.1 standard, *i.e.*, "maximum exposure duration resulting from the inherent design or intended use".

Where laser products are intended for viewing, it would normally be relatively easy to define a maximum likely (or even unlikely) exposure duration, and that duration would normally be less than 10^4 seconds. For this reason, and for consistency between standards, adoption of something similar to the ANSI approach would be recommended.

Proposal #7

FDA is considering changes to the tables in 21 CFR 1040.10(d) for the purpose of making the resulting classifications agree more nearly with the IEC and ANSI classifications. It is stated that the present structure of the tables will be maintained if possible because manufacturers are accustomed to it and because it is simpler than the corresponding ANSI and IEC tables.



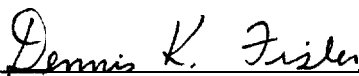
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Certainly the ANSI calculations are more complex, but if simplification results in some systems being considered more hazardous than they would be under the ANSI or IEC methods, the more complex should be used. The extra engineering cost of making the more complex calculation applies just once to each laser product, while the cost of the required mitigating features for a system that unnecessarily falls into a higher classification applies to each unit sold.

Other proposed amendments in this document seem to be reasonable and acceptable changes. If you have any questions, please contact Scott Hildum, the Laboratory's Laser Safety Officer at (510) 422-5263.


Dennis K. Fisher
Associate Director
Plant Operations

JSH:DKF:kdd

cc: HS 92-134
George Campbell
David Counts
Bill Silver
Scott Hildum
Date file



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From:



UNIVERSITY OF CALIFORNIA
LAWRENCE LIVE RMORE NATIONAL LABORATORY
P. O. BOX 808
LIVE RMORE, CALIFORNIA, 94551

To: Jerome E. Dennis, Chief
Light Products Branch
Division of Standards Enforcement
Offic of Compliance and Surveillance
Center for Device and Radiological Health
HFZ-312
1390 Piccard Drive
Rockville, MD 20750

